UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE OPINIONS OF KALIOPI PANAGOS, PHARM.D., R.Ph.

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Defendants Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., Actavis LLC, Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, "Defendants") respectfully submit this Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of Dr. Kaliopi Panagos pursuant to Federal Rules of Evidence 104, 403, 702, and 703 ("Motion").

INTRODUCTION

Plaintiffs proffer the opinion of Kali Panagos, Pharm.D., R.Ph., "regarding the type of information third party payors ('TPPs') rely on and consider when selecting generic drugs for inclusion on their formularies and subsequently paying for generic drugs and, more specifically, the generic Valsartan and Valsartan Containing Drugs at issue in this litigation." (10/31/22 Report ¶ 1.)[1] Dr. Panagos offers opinions on a wide range of topics, including prescription drug formularies, Medication Guides, and federal regulatory requirements for generic drug manufacturers—subjects far afield from those on which she can reliably opine. Additionally, many of Dr. Panagos's opinions are substantially similar, if not identical, to opinions that this Court has already reviewed and found to be

[1] A copy of Dr. Panagos's Expert Report (hereinafter, "10/31/22 Report") is attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit A**.

inadmissible at the class certification stage. For the reasons discussed herein, Dr. Panagos's opinions should be excluded.

First, exclusion of several of Dr. Panagos's opinions, including but not limited to her opinions concerning the purported formulary decision-making of the TPPs at issue (SummaCare, Inc. and EmblemHealth), is warranted under Rule 702 as they are unsupported and, therefore, unreliable. Dr. Panagos failed to verify information that is vital to her conclusions, including whether any nitrosamine impurities were ever found in the Reference Listed Drug ("RLD"). (1/11/23 Dep. 167:22-168:9, 169:6-15.)[2] Therefore, a conclusion that is foundational to her opinions—that the alleged presence of impurities in Valsartan Containing Drugs ("VCDs"), but not in the RLD, resulted in the VCDs no longer being equivalent to the RLD—hinges on unsupported assumptions and must be excluded. Dr. Panagos also has no knowledge of how the particular TPPs at issue here, SummaCare, Inc. and EmblemHealth, created their formularies. She has never worked for either entity, spoken to anyone at either entity, or reviewed any of their testimony or records concerning P&T committee decision-making. (*Id.* at 47:7-10, 81:8-15, 90:8-13, 117:18-22.) Again, Dr. Panagos is impermissibly relying on unsupported assumptions when she opines on how these TPPs select their formularies.

[2] Transcript of January 11, 2023 deposition of Kaliopi Panagos, Pharm.D., R.Ph. ("1/11/23 Dep."), attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit B**.

Furthermore, Dr. Panagos baselessly wades into regulatory topics such as the Abbreviated New Drug Application ("ANDA") process and Medication Guides despite her clear lack of knowledge on the subjects and lack of support for her conclusions.

Second, Dr. Panagos lacks the necessary experience and familiarity—and is therefore unqualified—to render several of her proffered opinions, including those concerning FDA regulatory requirements and processes, ANDAs, and Orange Book inclusion. Dr. Panagos has neither worked nor consulted for the FDA, nor consulted for a pharmaceutical or medical device manufacturer. (*Id*. at 46:21-23, 47:18-21.) Dr. Panagos's own testimony reveals she has never put together an ANDA, reviewed an ANDA, or approved an ANDA. (*Id.* at 91:24-92:9.) Further, the Orange Book itself clearly contradicts Dr. Panagos's conclusions about it, highlighting her basic misunderstanding of its purpose and meaning.

Third, Dr. Panagos offers several "opinions" that amount to no more than excludable and improper legal conclusions. Several times, Dr. Panagos impermissibly opines on ultimate issues, such as Defendants' statutory and regulatory compliance. In addition, Dr. Panagos uses terms such as "assurance" and "representation" (which she concedes are just substitutes for "warranty") in an attempt to render the same warranty-related "opinions" that this Court has already excluded.

***Fourth*,** Dr. Panagos should also be prohibited from offering opinions about whether or not ZHP complied with regulatory standards. These opinions do not appear in her report and must therefore be barred at trial.

Accordingly, and as explained in more detail below, Plaintiffs have failed to demonstrate the admissibility of any of Dr. Panagos's opinions, and the opinions should be excluded.[3]

BACKGROUND

Dr. Panagos was previously disclosed by Plaintiffs in the class certification phase of this litigation,[4] and Defendants moved to exclude her class certification opinions. On February 8, 2023, this Court issued its ruling on Defendants' Rule 702 motions at the class certification stage, excluding a number of Dr. Panagos's opinions because they lacked an adequate basis and because she opined on legal conclusions.

Now, disclosed again, Dr. Panagos is seeking to offer similar opinions that suffer from the same critical flaws requiring their exclusion. For example:

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[3] Defendants reserve the right to move to exclude or limit Dr. Panagos's opinions on grounds other than those set forth herein if those grounds become available after the filing of this Motion by virtue of the Court's rulings, any additional discovery that may take place in this case, or supplementation of Dr. Panagos's disclosure or 10/31/22 Report.

[4] A copy of Dr. Panagos's Class Certification Expert Report (hereinafter, "Class Report") is attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit C**.

- "If the generic manufacturer product changes in any way from the original product on the ANDA approval, then this changed product is not the same as the brand name medication (RLD)." (10/31/22 Report ¶ IV).

- "The generic drug label, insert, and pamphlets are no longer accurate insofar as the generic manufacturers are not meeting the obligations required by the regulations; the changed product cannot be deemed safe or effective and equivalence is nulled; and the generic manufacturer may no longer rely on the RLD." (*Id*. at ¶ V.)

- "PBMs establish formularies for generics based on the FDA approval process, and the information within the Orange Book tying these generics to their RLDs with the expectation that they are the same and/or therapeutically equivalent to the RLDs. TPPs reimbursed for these VCDs based on the assurances provided by the manufacturer in seeking approval and marketing the generics under the approved ANDA." (*Id*. at ¶ IX).

- "The assurances from the manufacturers of these products turned out to be false. TPPs paid for medications that they should not have based on the manufacturers' false representations. TPPs would not have selected these products for inclusion on their drug formularies or paid for these medications if they were aware of the potential presence of contaminants within the products." (*Id*. at ¶ X).

Indeed, many of the opinions included in the 10/31/22 Report can likewise be found—often verbatim—in Dr. Panagos's Class Report and suffer from the same critical flaws requiring their exclusion. (*See* Chart of Dr. Panagos's Excluded Class Certification Opinions and Their TPP Report Counterparts, attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit D)**.

For reasons detailed below, Dr. Panagos's opinions must once again be excluded.

LEGAL STANDARD

Under Federal Rule of Evidence 702, an expert must be qualified "by knowledge, skill, experience, training, or education . . . ." Fed. R. Evid. 702. Expert testimony from a qualified witness is admissible if: (1) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (2) it "is based on sufficient facts or data"; (3) it "is the product of reliable principles and methods"; and (4) the witness "has reliably applied the principles and methods to the facts of the case." *Id*; *see also* Fed. R. Evid. 104(a) ("The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible.").

In considering motions brought under Rule 702, this Court examines a "trilogy of restrictions on expert testimony: qualification, reliability and fit." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003)). The proponent of expert testimony must establish the admissibility of its expert's opinion by a preponderance of the evidence. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000). The district court must then, in turn, perform its "gatekeeping" function. At bottom, the court must "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The court's role in doing so is essential:

> "[T]he importance of [the] gatekeeping function cannot be overstated." *United States v. Barton*, 909 F.3d 1323, 1331 (11th Cir. 2018) . . . . That much is confirmed by the Advisory Committee on Evidence Rules' current proposal to amend Rule 702. On April 30, 2021, the Committee unanimously approved a proposal to amend Rule 702, part of which is motivated by its observation that in "a number of federal cases . . . judges did not apply the preponderance standard of admissibility to [Rule 702's] requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury." Advisory Comm. on Evidence Rules, *Agenda for Committee Meeting* 17 (Apr. 30, 2021) . . . . In order to address this "pervasive problem," *id.* at 18, both of the current draft amendments to Rule 702 would contain the following language in the advisory committee's notes:
>
> > [U]nfortunately many courts have held that the critical questions of the sufficiency of an expert's basis [for his testimony], and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a) and are rejected by this amendment.
>
> . . . That clearly echoes the existing law on the issue.

Sardis v. Overhead Door Corp., 10 F.4th 268, 283-84 (4th Cir. 2021) (second, fourth, fifth, seventh, and eighth alterations in original).

Additionally, Federal Rule of Evidence 403 states in part that a court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury." Fed. R. Evid. 403; *see also Ralston v. Garabedian*, Case No. 19-1539, 2022 U.S. Dist. LEXIS 49, at *6 (E.D. Pa. Jan. 3, 2022) (stating Rule 403 "applies to expert testimony"); *see also* Fed. R. Evid. 703 (disclosure of inadmissible information to

the jury is permitted "only if [its] probative value in helping the jury evaluate the opinion substantially outweighs [its] prejudicial effect").

ARGUMENT

I. DR. PANAGOS'S OPINIONS ARE LARGELY UNSUPPORTED AND THEREFORE EXCLUDABLE

An expert opinion is reliable if it is "based on the methods and procedures of science rather than on subjective belief or unsupported speculation" and the expert has "good grounds for his or her belief." *Calhoun*, 350 F.3d at 321 (citation and internal quotation marks omitted). An analysis having "good grounds" may include factors such as "whether a method consists of a testable hypothesis; . . . the existence and maintenance of standards controlling the technique's operation; . . . whether the method is generally accepted; . . . the relationship of the technique to methods which have been established to be reliable; . . . [and] the qualifications of the expert witness testifying based on the methodology." *In re Paoli R.R. Yard Pcb Litig.,* 35 F.3d 717, 742 n.8 (3d Cir. 1994); *see also id.* at 742 ("*Daubert* explains that the language of Rule 702 requiring the expert to testify to scientific knowledge means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or *unsupported speculation*'; the expert must have 'good grounds' for his or her belief") (quoting *Daubert*, 113 U.S. at 589-90) (emphasis added). Because the requisite "good grounds" have not been established for several of Dr. Panagos's opinions, their exclusion is warranted.

A. Dr. Panagos's Opinions That The VCDs Are Not The Same As The RLD Due To The Alleged Presence Of Impurities Are Unsupported

Dr. Panagos offers several opinions concerning the purported impact on "equivalence" and "sameness" between VCDs and the RLD due to the alleged presence of nitrosamine impurities in the former, but not the latter. For instance, she opines:

- "The presence of the contaminants rendered the manufacturer defendants' versions of VCDs . . . not the same as the branded product . . . ." (10/31/22 Report ¶ 105.)

- "The contaminants were not in the RLD, and therefore the generic products could not have been equivalent to the RLD due to the presence of the contaminants within the generic product." (*Id*. at ¶ 106).

- "[T]he changed product cannot be deemed safe or effective and equivalence is nulled; and the generic manufacturer may no longer rely on the RLD." (*Id*. at ¶ V.)

- "An ANDA would not have been issued if the presence of the contaminant was known because the presence of the contaminant would have been inconsistent in ingredients to the RLD and thus would not receive approval by the FDA." (*Id*. at ¶ XII.)

But in rendering these opinions, Dr. Panagos does not bother to actually confirm—or even check—whether the RLD was tested for nitrosamine impurities or whether any nitrosamine impurities were ever found in the RLD. Dr. Panagos simply assumes a fact that is essential to her conclusions: that the nitrosamine impurities were never in the RLD. This causes her opinions to be unsupported *ipse dixit* and, therefore, inadmissible.

Although her opinions hinge on the assumption that the RLD was free from nitrosamine impurities, Dr. Panagos conceded during her deposition that she did not know—or even consider relevant to her opinions—information that would be needed to support this assumption, such as whether: "the RLD was ever tested for NDMA [or NDEA] at any point prior to 2018"; "NDMA [or NDEA] w[ere] ever found in the Reference Listed Drug"; or "there was ever any recall of the RLD product." (1/11/23 Dep. 167:22-168:9, 169:6-15, 187:16-21.) Likewise, Dr. Panagos did not review, or even consider relevant to her opinions, key information supporting the other assumption underlying her opinions—*i.e.*, that the VCDs *did* contain nitrosamine impurities. Dr. Panagos testified that she never looked at the test results as to the level of NDMA and/or NDEA in individual VCDs, and did not consider those test results relevant to her opinions. (*See id*. at 187:22-190:16, 191:14-19.) As such, Dr. Panagos has no "good grounds" to support her various opinions that the alleged presence of nitrosamine impurities caused the generic VCDs to differ from the RLD.

Indeed, this Court recently excluded Dr. Panagos's opinions that the alleged presence of impurities in VCDs but not in the RLD resulted in the VCDs no longer being equivalent to the RLD and that "equivalence is nulled and the generic manufacturer may no longer rely on the brand name drug label." ECF 2261 at 94. Dr. Panagos asserts substantially the same opinions here. *See* Exhibit D at 1-2

(showing that ¶¶ 80, 102, 105, V, and IX in the 10/31/22 Report again impermissibly opine on bioequivalence issues).

Because Dr. Panagos's opinions that the VCDs differed from or were no longer equivalent to the RLD are wholly unsupported, and have been previously excluded by the Court in connection with her class certification opinions, the Court should once again exclude these opinions, which are now asserted in the 10/31/22 Report.

B. Dr. Panagos Has No Basis For Her Opinions Concerning The Decisions Of SummaCare, Inc. And EmblemHealth To Include VCDs On Their Drug Formularies And Reimburse For Purchases Of VCDs.

For the upcoming TPP trial, Dr. Panagos purports to offer on behalf of Plaintiffs expert opinions on the process by which TPPs select drugs for inclusion on a drug formulary and subsequently reimburse for their purchases. But the issue here involves not *all* drug-formulary and reimbursement decisions by *all* TPPs, but rather drug-formulary and reimbursement decisions about *VCDs* by *EmblemHealth and SummaCare, Inc*.[5]

[5] To the extent Dr. Panagos's opinions concern the *general* processes as to drug formulary inclusion and reimbursement by TPPs *other than* SummaCare, Inc. and EmblemHealth, they are irrelevant and do not "fit" this case. *See, e.g.*, *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 835 (3d Cir. 2020) (providing that expert testimony "fits" the dispute where it "will help the trier of fact . . . understand the evidence or . . . determine a fact in issue" (citations omitted)). This is another independent basis for their exclusion. *Id*. at 834-36 (holding that expert testimony should have been excluded in part because it "did not fit the case").

Dr. Panagos has no insight into how these TPPs created their drug formularies or reimbursed for VCD purchases. First, she has never worked for either EmblemHealth or SummaCare, Inc. (1/11/23 Dep. 90:8-13 ("Q. Have you ever worked for EmblemHealth? A. No. Q. Have you ever worked for SummaCare? A. No.").) Second, in rendering her opinions, Dr. Panagos did not review any materials indicating how these two TPPs' Pharmacy & Therapeutics ("P&T") committees made their decisions. (*Id*. at 117:18-22 ("Q. And you haven't reviewed any materials that indicate how the particular P&T committees of the TPPs in this litigation made their decisions; correct? A. Correct.").) And third, she did not review the testimony of any SummaCare, Inc. or EmblemHealth representative in drafting the 10/31/22 Report (nor did she think that those depositions would be relevant to her opinions). (*Id*. at 81:8-18 ("Q. Did you review any deposition testimony of any representative of SummaCare? A. No. Q. Did you review any deposition testimony of any representative of EmblemHealth? A. No. Q. If there were such depositions, would those be relevant to your opinions? A. No.").)

In fact, on at least one occasion, Dr. Panagos admitted to relying solely on Plaintiffs' counsel's representations to her in forming opinions related to SummaCare, Inc. and EmblemHealth. (*See id*. at 88:2-23 (conceding that plaintiffs' counsel was the sole basis for the statement that "It is my understanding that Express Scripts provided PBM services to Emblem Health from January 1, 2012 through

December 31, 2019 and that MedImpact provided PBM services to SummaCare from October 1, 2011 through December 31, 2018" at paragraph 27 of the 10/31/22 Report). But "[a]n expert must independently verify facts given to him, rather than 'accepting [them] at the word of . . . counsel,'" like Dr. Panagos did. *MDG Int'l, Inc. v. Australian Gold, Inc.*, Case No. 1:07-cv-1096, 2009 U.S. Dist. LEXIS 55652, at *13 (S.D. Ind. June 29, 2009) (second and third alterations in original) (quoting *Lyman v. St. Jude Med. S.C., Inc.*, 580 F. Supp. 2d 719, 726 (E.D. Wis. 2008)).

Dr. Panagos readily admits she has never worked for either SummaCare, Inc. or EmblemHealth. Neither has she spoken to anyone there about VCDs, or reviewed their depositions or records concerning P&T committee decision-making. (1/11/23 Dep. 47:7-10, 81:8-18, 90:8-13, 117:18-22.) Thus, by her own admissions, she is relying only on her belief as to how TPPs and P&T committees *generally* make decisions with respect to generic drugs.[6] Therefore, Dr. Panagos's opinions as to how SummaCare, Inc. and EmblemHealth *specifically* decided to include VCDs on their drug formularies and reimburse for their purchases are purely speculative and unsupported, and therefore excludable. (*See* 10/31/22 Report ¶¶ 20, 27, 30, 31, VIII, XIV.)

Indeed, the Court's February 8, 2023 Rule 702 ruling already excluded some

[6] For the reasons explained in Section II, Dr. Panagos is unqualified to opine even on the *general* decision-making of TPPs and P&T committees (let alone these *particular* TPPs), making this opinion even more unreliable.

of these opinions. For example, the Court excluded Dr. Panagos's opinion at paragraph G of the Class Report that "[t]he TPPs in this matter were all payors at risk for and made payments in connection with their insureds' purchases of VCDs." (ECF 2261 at 94; *see* Exhibit D at 2.) That opinion is reasserted verbatim in paragraph VIII of the 10/31/22 Report and should once again be excluded. The Court also excluded warranty-related opinions that reached the propriety of TPPs' payment of VCDs. (*See* ECF 2261 at 94 (excluding opinion in paragraph I of the Class Report); Class Report ¶ I ("The warranty from manufacturers for these products turned out to [sic] false. TPPs paid for medications that they should not have based on the manufacturers' false representation.").) Thus, Dr. Panagos's opinion in paragraph XIV of her 10/31/22 Report is also subject to exclusion based on the Court's prior ruling. (*See* 10/31/22 Report ¶ XIV ("In my professional opinion, the manufacturers' assurances as to these VCDs were false. The TPPs unjustly paid for medications for which they should not have paid. Manufacturers are accountable for the false assurances and representation of their drug products as equivalent to their RLDs.").)

Because Dr. Panagos has no "good grounds" to support her beliefs on how the TPPs at issue in this trial made their decisions concerning the inclusion of VCDs on drug formularies and reimbursement of VCD purchases, her opinions should be excluded as unreliable.

C. Dr. Panagos Has No Basis For Several Of Her FDA-Related Opinions

Dr. Panagos's 23-page report contains a number of opinions that are premised on her characterization of FDA regulations and processes, but support for the vast majority of those opinions cannot be found in the 10/31/22 Report or Dr. Panagos's related testimony. Without such a basis, Dr. Panagos should not be permitted to render those opinions. *See Calhoun*, 350 F.3d at 321 (explaining that expert opinion cannot be based on "unsupported speculation").

1. Dr. Panagos's Opinions On The ANDA Approval Process And The Duties Of Generic Drug Manufacturers With Respect To That Process Are Unsupported

Dr. Panagos's characterization of FDA regulations as to ANDA approval and manufacturers' compliance therewith underlie several of her opinions, including the following, yet Dr. Panagos does not cite to any FDA regulations as support for these conclusions stated in the 10/31/22 Report:

- "The supply chain must be solid and for approval of an ANDA, Good Manufacturing Practices and inspection reports are considered." ((10/31/22 Report ¶ 46) (footnote omitted).)[7]

- "Generic drug manufacturers have to comply with certain FDA requirements to receive ANDA approval, which includes ensuring that their medications are safe and effective." (*Id*. at ¶ 67.)

- "Approved generic drugs are required to be bioequivalent and

[7] As support for this opinion, Dr. Panagos cites to an FDA webpage (attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit E)** that contains various links but no discussion of supply chains, Good Manufacturing Practices, or inspection reports. Thus, this paragraph remains unsupported.

> therapeutically equivalent to their brand name counterparts." (*Id*. at ¶ 87.)

- "Any changes to a generic drug product from the RLD are required to be reported to the FDA." (*Id*. at ¶ 107.)

Dr. Panagos also could not identify any specific FDA regulation upon which she relied when asked to do so at her deposition. (*See, e.g.*, 1/11/23 Dep. 94:23-95:10.) Instead, she testified that she considered "specific federal regulations for ANDA submission" to be "outside the scope" of her opinions. (*Id*. at 95:6-10.) Remarkably, she also testified that details of the ANDA process—a process she references over and over in the 10/31/22 Report—are similarly outside the scope of her opinions:

> Q. Is there an independent showing of safety and effectiveness separate from the RLD that needs to be demonstrated by the ANDA -- by the entity that's submitting the ANDA?
>
> . . .
>
> A. The -- the details of the ANDA process were outside of the scope of this opinion….

(*Id.* at 120:18-121:8.)

In other words, she states that the only material that could provide the requisite "good grounds" for her opinions is something that she considered to be outside the scope of her opinions. Thus, by her own testimony, Dr. Panagos has no possible basis to support these opinions, and they should be excluded. (10/31/22 Report ¶¶ 39–46, 50, 64–69, 76, 84–90, 96–98, 105–08, I–V, XII–XIII.)

Indeed, this Court has already rejected at the class certification stage several of Dr. Panagos's FDA regulatory opinions, which are reiterated (often verbatim) in the 10/31/22 Report. Specifically, the Court's February 8, 2023 ruling precluded Dr. Panagos's opinions that:

- "Manufacturers are responsible for understanding their processes which includes preventing the presence of unacceptable and impurities." (Class Report ¶ 52.)

- "They are responsible for developing and using suitable methods to detect and limit unacceptable impurities, including any new impurities that may arise when they make changes to their manufacturing processes." (*Id*. at ¶ 53.)

- "The presence of the contaminant rendered the manufacturer defendants' versions of VCDs **not** equivalent to the branded product as indicated in the Orange Book which serves as the source of truth for bioequivalence." (*Id*. at ¶ 59.)

- "If the generic manufacturer product changes in any way from the original product on the ANDA approval, then this changed product is not the same as the brand name medication; equivalence is nulled and the generic manufacturer may no longer rely on the brand name drug label." (*Id*. at ¶ D.)

ECF 2261 at 94. Because these opinions were reasserted—at times, verbatim—in the 10/31/22 Report (*see* Exhibit D at 1, 2; *see also* 10/31/22 Report ¶ 96, 97, 105, IV, and V), they should likewise be excluded, just as they were at the class certification stage.

2. Dr. Panagos Lacks Support For Her Opinions Concerning Medication Guides

Dr. Panagos opines that "[t]he manufacturers of the VCDs did not indicate that NDMA or NDEA were in their products . . . in the medication guide . . . ," which is "a misrepresentation of their product and a deviation from current Good Manufacturing Practices." (10/31/211 Report ¶ 133.) But Dr. Panagos does not, and cannot, have a basis for that opinion, as Medication Guides are not applicable to VCDs.[8]

[8] According to the FDA, "Medication Guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events. . . . . FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that . . . certain information is necessary to prevent serious adverse effects . . . [,] patient decision-making should be informed by information about a known serious side effect with a product, or . . . patient adherence to directions for the use of a product are essential to its effectiveness." *See* Medication Guides – Providing information on proper drug use, safety, and storage, https://www.fda.gov/drugs/drug-safety-and-availability/medication-guides (last visited Mar. 6, 2023); *see also, e.g.*, *Desai v. Sorin CRM USA, Inc.*, Case No. 12-2995, 2013 U.S. Dist. LEXIS 5795, at *10 (D.N.J. Jan. 15, 2013) ("This Court takes judicial notice of the FDA's website . . . ."). When required for a particular drug, the Medication Guide forms part of the FDA-approved labeling for that drug. *See* Patient Labeling Resources - For Industry, https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#:~:text=A%20Medication%20Guide%20is%20patient,help%20prevent%20serious%20adverse%20reactions (last visited Mar. 6, 2023) ("A Medication Guide is patient labeling that is part of the FDA-approved prescription drug labeling for certain prescription drugs . . . ."). As such, a generic drug manufacturer would not be able to add a Medication Guide unless it is part of the FDA-approved labeling for the RLD. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 605, 618 (2011) (holding that generic manufacturers cannot independently change labeling because it would

Although she is admittedly aware that "the FDA maintains a database of drugs that require Medication Guides," Dr. Panagos did not check that database to ensure Medication Guides were required for the VCDs at issue before asserting that Defendants somehow misrepresented information on non-existent (and not required) Medication Guides. (*See* 1/11/23 Dep. 173:14-17, 174:24-175:6.)[9] Dr. Panagos also conceded that she was not "personally aware one way or the other of FDA ever requiring the Medication Guide be included with any VCD." (*Id*. at 178:14-20.)

Furthermore, Dr. Panagos's testimony relating to Medication Guides confirms that she does not actually know what Medication Guides are or when they are used. Specifically, Dr. Panagos appears to believe a Medication Guide is generally any sort of "guide" or information available to a patient "to refer to" to "understand how to use their medication"—including "the information that's typically stapled to the outside of the bag when you pick up a prescription at a pharmacy"—rather than an FDA term of art for a particular aspect of prescription drug labeling that is required

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violate federal requirements that generic labeling be the same as corresponding RLD labeling).

[9] When presented with a printout of that database during her deposition, Dr. Panagos conceded that no VCD was listed therein. (1/11/23 Dep. at 176:11-177:19.) Thus, Dr. Panagos's opinions concerning Medication Guides are also excludable as irrelevant, because opinions concerning a type of labeling that is inapplicable to the products at issue cannot possibly be "sufficiently tied to the facts of the case" or otherwise helpful for the jury to "determine a fact in issue." *UGI Sunbury LLC*, 949 F.3d at 832, 835.

by FDA for certain prescription drugs in certain circumstances.[10] (*Id*. at 170:15-171:16.)

Because Dr. Panagos lacks a basis for her opinions on Medication Guides (10/31/22 Report ¶¶ 129-33), they should be excluded.

D. The Opinions For Which Dr. Panagos Fails To Identify A Basis Are Unreliable And Should Be Excluded

Dr. Panagos's failure to provide support for her opinions is not limited to the categories of opinions discussed above, but rather permeates the 10/31/22 Report. (*See* 10/31/22 Report ¶¶ 13, 15-19, 21-26, 28-29, 33-36, 47-49, 51-63, 71-75, 77-79, 81-83, 91-95, 100, 103-04, 109-15, 117-26 (providing no footnotes, citation, or other reference to a supporting source).) When asked to clarify the bases for her opinions during her deposition, she often broadly relied on her background, education, and experience, as well as the entirety of the reliance list appended to the 10/31/22 Report, until pressed for more information. But "experts must explain precisely how they went about reaching their conclusions and point to some objective source . . . to show that they have followed the scientific method," rather than just referring

[10] Federal regulations make clear that Medication Guides must contain specific information, must be approved by the FDA, and are only required if a drug meets certain criteria. *See* 21 C.F.R. § 208.1(c), § 208.20, § 208.24(a); *see also* 12/19/22 Report of Timothy E. Kosty ¶ [redacted] attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit F**.

counsel to a list of sources. *Daubert v. Merrell Dow Pharms., Inc*., 43 F.3d 1311, 1319 (9th Cir. 1995).

Moreover, Dr. Panagos behaves as though her background as a pharmacist and benefits consultant singularly enables her to opine on issues far beyond what her limited knowledge and experience actually enable. For instance, Dr. Panagos was asked at her deposition for the basis for paragraph 18 of the 10/31/22 Report, which states that "[a]nimal studies have found that NDMA caused liver and lung cancer, as well as other cancers." (1/11/23 Dep. 76:21-77:2.) Dr. Panagos identified in response, in addition to IARC information, her "background and education and experience as a clinical pharmacist," as well as "one or more or all" of the references in Appendix A to the 10/31/22 Report. (*Id*. at 77:3-78:9.) Dr. Panagos has no background in pathology, and she is not an oncologist or medical doctor of any sort. Nor is there any indication she has performed research on cancer-causing elements and/or performed or analyzed animal studies. As such, there is not a single justification for Dr. Panagos's background alone being a proper basis for this opinion.

And when Dr. Panagos *did* specifically cite a source in the 10/31/22 Report as providing the basis for an opinion, a close reading of that source revealed that it did *not* support her assertion. For example:

- In paragraph 70(b) of the 10/31/22 Report, Dr. Panagos purports to identify as a "factor[] and source[] of information" that P&T

committees consider for formulary inclusion purposes "FDA-approved prescribing information and related FDA information including safety data (this will come from the ANDA which includes the information provided by the manufacturer)". But, as acknowledged at her deposition, the information within that parenthetical is nowhere to be found in the source upon which Dr. Panagos relies for this paragraph. *See* Formulary Management, AMCP, *available at* https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-carepharmacy/formulary-management (last visited Mar. 6, 2023); *see also* 1/11/23 Dep. 124:19-125:14, 126:6-15.

- In paragraph 46 of the 10/31/22 Report, Dr. Panagos opines that "[t]he supply chain must be solid and for approval of an ANDA, Good Manufacturing Practices and inspection reports are considered." The support identified for this opinion is an FDA webpage with various links, but with no discussion specifically on supply chains, Good Manufacturing Practices, or inspection reports. *See* **Exhibit E**.

- Paragraph 37 of the 10/31/22 Report provides that "[m]embers of a P&T committee are subject to completion of a 'conflict of interest' disclosure form as well as a 'non-disclosure' annual agreement." Dr. Panagos cites to a CVS Caremark document[11] for support for this statement, but there is no reference in that document to non-disclosure agreements.

In short, this Court should exclude those opinions of Dr. Panagos that lack support, as "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

[11] A copy of "CVS Caremark – Formulary Development and Management at CVS Caremark" is attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit G**.

II. DR. PANAGOS IS UNQUALIFIED TO RENDER THE OPINIONS IN HER REPORT

In determining if the qualifications of a given expert form a sufficient basis from which to render their opinion(s), "[t]he focus . . . is on whether the qualifications that an expert does have provide a foundation for the witness to testify meaningfully on a given matter." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, MDL No. 2445 13-MD-2445; Case No. 16-5073, 2020 U.S. Dist. LEXIS 219949, at *18-19 (E.D. Pa. Nov. 24, 2020). It is Plaintiffs' burden to show Dr. Panagos has the requisite qualifications to render her opinions. *See, e.g., Wicker v. CONRAIL*, 371 F. Supp. 2d 702, 726 (W.D. Pa. 2005) (disqualifying expert opinions in part because of "the lack of evidence as to qualifications," noting that "[p]roduction of such evidence is the burden of the proponent of the evidence"). Plaintiffs have *not* shown that Dr. Panagos's qualifications provide that necessary foundation.

A. Dr. Panagos Lacks The Qualifications To Opine On FDA-Related Issues

Dr. Panagos offers multiple opinions on FDA-related issues, including Medication Guides, the regulatory application process by which generic drugs are reviewed and approved by the FDA (ANDAs), and manufacturers' duties with respect to the ANDA process. Dr. Panagos—having no experience working with any of these issues, either on behalf of the FDA or a generic manufacturer—is plainly unqualified to offer any of those opinions.

Indeed, Dr. Panagos has never worked for or consulted with the FDA, and she has never done any consulting work for a pharmaceutical or medical device company. (1/11/23 Dep. 46:21-23, 47:18-21.) She has never even published on or studied FDA regulatory issues more generally. (*Id.* at 43:23-44:2, 44:8-11; 1/21/22 Dep. 56:16-17.)[12] She has also never been involved with putting together or submitting an ANDA, or reviewing or approving one. (1/11/23 Dep. 91:24-92:9.) When asked about her self-professed "experience in the ANDA approval process," she admitted it is limited to "[u]nderstanding what the importance of the ANDA is as it pertains to generic drugs." (*Id.* at 91:4-15.) In other words, simply understanding that an ANDA approval is required for a generic drug to be marketed in the U.S. (*Id.* at 91:16-23 ("Q. So in your view, the importance of the ANDA is that it is required for FDA approval and for inclusion in the Orange Book? A. It is required – it's submitted by manufacturers to be considered for approval by the FDA and inclusion into the Orange Book.").) This is not sufficient to qualify her to render substantive opinions about the ANDA process or manufacturers' duties with respect thereto.

Additionally, Dr. Panagos has no experience or training qualifying her to testify about Medication Guides. Nor does she have any knowledge of whether or

[12] Transcript of January 21, 2022 deposition of Kaliopi Panagos, Pharm.D., R.Ph. ("1/21/22 Dep."), attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit H.**

not they were even required (they were not) for the VCDs at issue. (*Id*. at 178:14-20 ("Q: So, Doctor, are you personally aware one way or the other of FDA ever requiring the Medication Guide be included with any VCD? A. No . . . .").)

Dr. Panagos's utter lack of experience in regulatory affairs in any capacity, which is glaringly evident from her testimony, renders her unqualified to opine on any such issues. Therefore, all opinions that relate to regulatory requirements must be excluded due to her lack of qualification.

B. Dr. Panagos Is Unqualified To Opine On The Type Of Information TPPs Rely On When Considering For Formulary Inclusion And Reimbursing For Generic Drugs

Plaintiffs have not shown that Dr. Panagos has sufficient experience creating drug formularies or reimbursing for purchases of the drugs listed therein to qualify her to render the opinions in the 10/31/22 Report. As a pharmacy benefit consultant, Dr. Panagos works *with* clients that create and manage drug formularies—*she* does not create and manage drug formularies. In fact, Dr. Panagos has only *once* in her career held a role where she directly created and managed formularies—and that employment happens to be the shortest employment on her entire CV. (1/21/22 Dep. 34:13-35:3; *see also* 1/11/23 Dep. 46:24-47:6 ("Q: Have you had any other experience or training since your prior deposition in this case that is relevant to the opinions you are rendering in this case and that we have not already discussed today? A: No.").) That limited experience does not qualify Dr. Panagos to testify as to how

TPPs and P&T committees generally determine formulary drug inclusion and reimbursement.

Dr. Panagos herself testified that, "[f]ormularies are developed by the P&T committees, the respective organization that is putting together the formulary." (*Id.* at 104:14-16.) Yet Dr. Panagos has never served as a member of a P&T Committee (*id.* at 117:15-17), nor has she worked for a TPP (1/21/22 Dep. 42:18-19; 1/11/23 Dep. 46:24-47:6 (stating no further relevant experience or training since her 1/21/22 deposition)), nor has she identified any other basis for her to be considered qualified in this area. As such, she lacks the necessary qualifications to offer expert testimony on how these entities decide to include drugs on formularies and later reimburse for their purchases.

C. Dr. Panagos Is Not Qualified To Opine On The Process By Which Drugs Are Included In The Orange Book

Dr. Panagos's *general* familiarity with the Orange Book does not qualify her as an expert to opine on the *specific* process by which a drug is included in the Orange Book. Dr. Panagos has never been involved with the decision to include a drug in the Orange Book. (1/11/23 Dep. 92:10-13 ("Q: Have you ever been involved with inclusion -- with the decision to include a drug in the Orange Book? A: No.").)

Indeed, her testimony directly contradicts *what the Orange Book itself says* about what the inclusion of a drug does and does not mean. Specifically, Dr. Panagos testified that "if there was a deviation from therapeutic equivalence, the drug would

absolutely not be in the Orange Book" (*id.* at 162:2-4), but the Orange Book preface specifically states that "[i]nclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product." *See* Orange Book Preface (43rd ed.), *available at* https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last visited Mar. 6, 2023). Accordingly, her testimony is contradicted by the Orange Book itself, which highlights her utter lack of knowledge and qualifications to opine on the subject.

III. DR. PANAGOS'S LEGAL CONCLUSIONS ARE NOT THE PROPER SUBJECT OF "EXPERT OPINIONS" AND MUST BE EXCLUDED

Expert opinions that invade ultimate issues in the case are excludable legal conclusions. For instance, experts may not opine on "whether Defendant was in regulatory compliance with the FDA." *Stanley v. Novartis Pharms. Corp.*, Case No. 11-03191, 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014); *see also In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 2436, 2016 U.S. Dist. LEXIS 98858, at *8–9 (E.D. Pa. July 27, 2016) (barring an expert opinion on whether a drug met an FDA regulatory standard). Nor can expert witnesses opine on "the ultimate legal conclusion" in a case. *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013); *see also Peroza-Benitez v. Smith*, Case No. 17-3980, 2019 U.S. Dist. LEXIS 130012, at *3 (E.D. Pa. Aug. 2, 2019) ("Rule 702 prohibits opinions which would merely tell the jury what result to

reach.") (citation and internal quotation marks omitted), *rev'd on other grounds*, 994 F.3d 147 (3d Cir. 2021). Dr. Panagos renders a number of such "opinions," which must be excluded.

A. Dr. Panagos's "Opinions" Concerning Defendants' Statutory and Regulatory Compliance are Improper Legal Conclusions

Dr. Panagos offers several opinions concerning whether Defendants complied with applicable statutory and regulatory requirements. For example, Dr. Panagos opines that:

- "The presence of the contaminants rendered the manufacturer defendants' versions of VCDs unsafe and not the same as the branded product as indicated in the Orange Book . . . ." (10/31/22 Report ¶ 105.)

- "The contaminants were not in the RLD, and therefore the generic products could not have been equivalent to the RLD due to the presence of contaminants within the generic product." (*Id*. at ¶ 106.)

- "The contaminated VCDs were inconsistent with the ANDAs submitted for approval." (*Id*. at ¶ 108.)

- "The manufacturers of the VCDs did not indicate that NDMA or NDEA were in their products in the package insert, in the medication guide, or on the prescription label. This represents . . . a deviation from current Good Manufacturing Practices." (*Id*. at ¶ 133.)

- "The presence of the carcinogenic contaminants was a clear and significant deviation from the required manufacturer compliance and obligation to safety." (*Id*. at ¶ II.)

- "The generic drug label, insert, and pamphlets are no longer accurate insofar as the generic manufacturers are not meeting the obligations required by the regulations; the changed product cannot be deemed

safe or effective and equivalence is nulled; and the generic manufacturer may no longer rely on the RLD." (*Id*. at ¶ V.)

- "An ANDA would not have been issued if the presence of the contaminant was known because the presence of the contaminant would have been inconsistent in ingredients to the RLD and thus would not receive approval by the FDA." (*Id*. at ¶ XII.)

Indeed, this Court has previously excluded at the class certification stage some of the opinions identified above. *See* Exhibit D at 1, 2 (comparing 10/31/22 Report ¶¶ 105 and V with Class Report ¶¶ 59 and D, respectively); *see also* ECF 2261 at 94. Because each of the "opinions" listed above are no more than Dr. Panagos's belief as to "whether Defendant[s] w[ere] in regulatory compliance with the FDA," they are impermissible legal conclusions and must be excluded. *Stanley*, 2014 U.S. Dist. LEXIS 198861, at *10.

B. Dr. Panagos's "Opinions" Concerning Alleged Representations and Assurances by Defendants, TPPs' Alleged Reliance Thereon, and The Propriety of TPPs' Payment of VCDs Are Improper Legal Conclusions

On several occasions, Dr. Panagos also opines on legal issues that are best determined by the factfinder. For example, Dr. Panagos opines that:

- "A drug's 'AB' listing in the Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's assurance to TPPs and P&T Committees that the generic drug is equivalent to the brand drug for placement on a prescription drug formulary." (10/31/22 Report ¶ 80.)

- "P&T committees and TPPs rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan." (*Id*. at ¶ 99.)

- "When third party payors agree to reimburse for generic drugs such as valsartan including VCDs, they do so based on representations made by manufacturers that their drug product is in compliance with the FDA, bioequivalent of the Orange Book reference drug and safe to be sold to consumers." (*Id*. at ¶ 102.)

- "In the case of valsartan, including VCDs, the representations made by the manufacturers were false. As such, TPPs paid for medications they should not have paid for . . . ." (*Id*. at ¶ 103.)

- "TPPs are entitled to rely on a manufacturer's compliance with Orange Book standards when reimbursing for what was represented as generic valsartan, including VCDs." (*Id*. at ¶ 104.)

- "The manufacturers of the VCDs did not indicate that NDMA or NDEA were in their products in the package insert, in the medication guide, or on the prescription label. This represents a misrepresentation of their product . . . ." (*Id*. at ¶ 133.)

- "TPPs reimbursed for these VCDs based on the assurances provided by the manufacturer in seeking approval and marketing the generics under the approved ANDA." (*Id*. at ¶ IX.)

- "The assurances from the manufacturers of these products turned out to be false. TPPs paid for medications that they should not have based on the manufacturers' false representations . . . ." (*Id*. at ¶ X.)

- "[T]he manufacturers' assurances as to these VCDs were false. The TPPs unjustly paid for medications for which they should not have paid. Manufacturers are accountable for the false assurances and representation of their drug products as equivalent to their RLDs." (*Id*. at ¶ XIV.)

Once again, this Court has *already* excluded several of the opinions identified above and should do so once more. *See* Exhibit D at 1-2 (comparing 10/31/22 Report ¶¶ 80, 99, 102, 103, 104, IX, and X with Class Report ¶¶ 47, 55, 56, 57, 58, H, and I,

respectively); *see also* ECF 2261 at 94. Plaintiffs assert against Defendants claims of, *inter alia*, breach of express warranty, fraud, violations of state consumer protection laws, negligent misrepresentation, and unjust enrichment. *See* Third Am. Consolidated Economic Loss Class Action Compl. ¶¶ 619-32, 688-739, 780-97, ECF 1708. In each of the above "opinions," Dr. Panagos "merely tell[s] the jury what result to reach" on those claims; therefore, these "opinions" should be excluded. *Peroza-Benitez*, 2019 U.S. Dist. LEXIS 130012, at *3 (internal quotation marks and citation omitted); *see id*. at *5-8 (excluding expert report on the basis that it opined on ultimate issue before jury).

C. Dr. Panagos Concedes That Her "Assurance" And "Representation" Opinions About the Orange Book Are The Same As Her Excluded "Warranty" Opinions

At the class certification stage, the Court granted Defendants' motion to exclude Dr. Panagos's "warranty" opinions, holding that:

> Dr. Panagos . . . opines that an Orange Book TE code on a generic drug expresses a warranty from the generic's manufacturer . . . to TPPs and P&T Committees . . . that the generic is equivalent to the RLD. As the Court has found for other experts, **whether TE codes and subcodes constitute a warranty is a legal question to be posed to, and answered by, the factfinder after a review of relevant facts. Therefore, Dr. Panagos's opinion as to TE codes serving as a mfr's [sic] warranty is outside the purview of her expertise**.

ECF 2261 at 94 (emphasis added); *see also id*. (excluding the following warranty-related opinions from the Class Report: ¶¶ 47, 55-58, B, H, and I).

In what is possibly an attempt to prevent Defendants from reasserting this very argument, Dr. Panagos replaced the term "warranty" with the terms "assurance" and "representation" when copying and pasting several of the warranty-based opinions from her *Class Report* into the 10/31/22 Report, and when asserting *new* warranty-based opinions. (10/31/22 Report ¶¶ 80, 102, 103, part of I, part of IX, part of X, and XIV; *see also id*. at ¶¶ 81, 84.) But this cannot save her opinions from exclusion. Indeed, Dr. Panagos herself acknowledges that—in terms of how she has used these words in the 10/31/22 Report—the terms "assurance" and "representation" really just mean "warranty":

> **And so assurance or warranty, they really mean the same thing**. It's the promise that the manufacturers make, validation that their product is identical to the brand product, does not deviate in any way in safety and effectiveness, and -- and that's why I -- **whether it's warranty or assurance, it really denotes the same -- the same thing**.

(1/11/23 Dep. 140:23-141:7.)[13]

Dr. Panagos concedes that her "assurance" and "representation"-based opinions are warranty-based opinions dressed up in different clothing.[14] These

[13] Dr. Panagos testified similarly during her 1/21/2022 deposition. (*See* 1/21/22 Dep. 123:2-7 (explaining that, as used in the Class Report, "warranty" was "a term that refer[red] to a promise, an assurance, a guarantee that that manufacturer has set forth").)

[14] The *Patrick* case is instructive. 536 F. App'x at 258 (upholding the exclusion of testimony of a police expert who "essentially opined that [the defendant's] actions were unreasonable"). There, the court upheld the exclusion of the testimony of a police expert in a 1983 excessive force suit who opined that a deputy sheriff's use of a taser was unreasonable. The court held that "'reasonableness' is practically

opinions should therefore be excluded for the same reason that this Court excluded Dr. Panagos's warranty-based opinions at the class certification stage.[15] *See* 10/31/22 Report ¶¶ 80, 81, 84, 102, 103, I, IX, X, XIV (paragraphs of the 10/31/22 Report that should be excluded as warranty-based opinions); *see also* Exhibit D at 1-2.

IV. DR. PANAGOS MAY NOT OFFER OPINIONS ABOUT ZHP NOT DISCLOSED IN HER REPORT

Dr. Panagos should also be prohibited from offering opinions about whether or not ZHP complied with regulatory standards because such opinions are not included in her expert report. Rule 26 provides that an expert's report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). It is "axiomatic that an expert may not present new opinions on topics not timely included or otherwise disclosed in the expert's report." *Krys v. Aaron*, 112 F. Supp. 3d 181, 207 (D.N.J. 2015); *see also*

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interchangeable with 'excessiveness', so [the expert] might as well have opined that [the deputy's] use of force was excessive." *Id.* Likewise, here, the "assurance" and "representation" testimony is tantamount to the "warranty" opinions that this Court has already excluded as an ultimate issue in the case.

[15] Additionally, Dr. Panagos is not permitted to step into the shoes of any Defendant to opine on whether they *intended* to make an assurance (or representation or warranty), to the extent she attempts to do so. *See, e.g.*, *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 U.S. Dist. LEXIS 9037, at *28–30 (E.D. Pa. June 20, 2000) (excluding opinions regarding a drug company's "corporate intent," as "[t]he question of intent is a classic jury question and not one for experts").

Johnson v. Vanguard Mfg., Inc., 34 F. App'x 858, 859 (3d Cir. 2002) (affirming exclusion of expert opinion not disclosed in report).

Dr. Panagos's report does not contain any substantive discussion of ZHP's conduct, whether it complied with cGMPs, or whether its API conformed to regulatory standards. At her deposition, Dr. Panagos initially confirmed that she did not intend to opine at trial regarding ZHP, its conduct, or its API, testifying that her "opinions are referring to the manufacturers who submitted the ANDA[s]" for VCDs[16] (1/11/23 Dep. 194:23-195:7) and that "**API manufacturers were not within the scope of my report here**," (*id.* at 195:8-12 (emphasis added)).

Following a speaking objection from plaintiffs' counsel, however, Dr. Panagos changed her testimony, stating that she was offering opinions with respect to all manufacturers, including manufacturers of API, who "had contaminants in their drug product" and whose products were therefore "not equal, same or safe to the Reference Listed Drug product." (*Id*. at 195:13-196:20, 197:22-198:14, 199:15-23.) Such opinions do not appear anywhere in Dr. Panagos's report – and it is well

[16] In one of only two references to ZHP in the 10/31/22 Report, Dr. Panagos inaccurately stated that [redacted] but ZHP is an ***API manufacturer*** and therefore never submitted an ANDA for a VCD. (*See, e.g.*, 10/31/2022 Report of Laura M. Plunkett, Ph.D., DABT ¶ 54, attached to the accompanying Certification of Victoria Davis Lockard, Esq. as **Exhibit I** (Plaintiffs' expert noting that none of the ANDAs at issue were filed by ZHP).) Dr. Panagos conceded as much at her deposition. (*See* 1/11/23 Dep. 195:8-12.)

recognized that "Rule 26(a)(2) does not allow parties to cure deficient expert reports by supplementing them with later deposition testimony." *Ciomber v. Coop. Plus, Inc*., 527 F.3d 635, 642 (7th Cir. 2008). Accordingly, Dr. Panagos should be barred from offering any opinions regarding ZHP or its compliance with regulatory standards at trial.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant this Joint Motion to Exclude the Opinions of Dr. Kaliopi Panagos and enter an Order excluding the opinions of Dr. Panagos.

Dated: March 13, 2023

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on March 13, 2023, a copy of the foregoing document was servedon all counsel of record via CM/ECF.

By: */s/ Steven M. Harkins*
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